U.S. Environmental Protection Agency
Science Advisory Board
Metals Assessment Panel
Final Minutes of Public Conference Call Meeting Sept 10-12, 2002

Committee: Metals Assessment Panel of the U.S. Environmental Protection Agency's Science Advisory Board (SAB). (See attached Roster)

Date and Time: September 10-12 (See attached Federal Register Notice)

Location: Hilton Crystal City at Ronald Reagan National Airport, 2399 Jefferson Davis Highway, Arlington, VA 22202 (Tel. 703-418-6800)

Purpose: Three conference call meetings, preceding this face-to-face meeting were announced in 67 FEDERAL REGISTER, Number 46505-46506, July 15, 2002. This meeting was announced in 67 FEDERAL REGISTER, Number Page 53584-53585, August 16, 2002. The purpose of this meeting was for the Panel to complete its review of EPA's draft Action Plan for the ``Framework for Metals Assessment and Cross-Agency Guidance for Assessing Metals-Related Hazard and Risk."

Materials Available: In addition to materials provided before or at the August 29, 2002 conference call of the panel, the panel received the following materials before the meeting:

1. the agenda for the meeting

2. revised preliminary comments from individuals on the SAB Metals Assessment Panel

3. the SAB's report, Toward Integrated Environmental Decision Making

4. EPA's Framework for Ecological Risk Assessment, Guidelines for the Health Risk Assessment of Chemical Mixtures, and Supplementary Guidance for conducting Health Risk Assessment of Chemical Mixtures.

5. A CD with Experts Workshop Review of the State-Of-The-Science Regarding PBT Concepts and Metals and Metal Compounds (January 19, 2000) from John Arnett of the Copper & Brass Fabricators Council, Inc.

The Panel received the following materials at the meeting:

6. Overheads used by Kevin Bromberg of US Small Business Administration (SBA) Office of Advocacy in his presentation.

7. Mertz, W. 1993. Essential Trace Metals: New Definitions Based on New

Paradigms. *Nutrition Reviews* 51(10):287-295.

8. Panel Draft prepared September 10 and distributed on the morning of September 11

9. Panel Draft prepared and distributed on the afternoon of September 11

10. Panel Draft distributed on the morning of September 12.

All these materials are found in the FACA file for this meeting. Panel comments and drafts were made available to the Agency and the Public at the same time they were distributed to the panel with the exception of the first draft of the cover letter, for which too few copies were made. This letter was read out loud so all present could know what was being discussed.

NOTE: All review materials are posted at the Risk Assessment Forum Website (http://cfpub.epa.gov/ncea/raf/rafpub/cfm?ActType=default). They include the draft Metals Action Plan, five public comments on the Action Plan, and the summary of a meeting held February 20, 2002. The announcements for the meetings, agendas, hand-outs distributed at the meetings, and biosketches for the panelists can be found at the Science Advisory Board's website (http://www.epa.gov/sab/metalspanel.html)
The Panel's approved draft, forwarded to the Executive Committee for consideration at the October 1-2 meeting is also posted at the SAB website, but in a different location. (http://www.epa.gov/sab/pdf/metalsdraft91802.pdf)

Attendees (Summary):
The Panel and DFO were present for the whole meeting. Others came and left. This list of attendees includes those who were present for any part of the meeting. The affiliations of the panelists can be found on the attached roster, those of other attendees on the attached sign-in sheets.

Panel: Drs: Thomas, Friedland, Fowler, Hayes, O'Rourke, Pittinger, Tran, Weis, Windom.

SAB Staff: Kathleen White, Zisa Lubarov-Walton, James Rowe, Sue Shallal, and Vanessa Vu

EPA Staff: Bill Wood, Kevin Minoli (OGC), Stephen DeVito, Charles DeLos (OW), Marc Stifelman (Region 10), Randy Wentzel, Alec McBride (OSW), Keith Sappington, Larry Rosengrant (OSW)

Members of the Public: Bill Adams of Rio Tinto, Meredith Preston of BNA, Ann Smith-Reiser of Analytical Services, Jane Luxton of King and Spalding, John Arnett of the Copper& Brass Fabricators Council, Melvin Keener of CRWI, Cheryl Hogue of C&EN, Mario Gamboa of the American Chemistry Council, Sueanne Pfifferling of Pfifferling and Associates, Hugh Morrow of the

International Cadmium Association, Craig Boreiko (international Lead Zing Research Organization), Ann Smith-Reiser (Analytical Services, Inc.)

Feds: Kevin Bromberg of US Small Business Administration (SBA) Office of Advocacy

Summary

At this meeting the Panel heard briefings from EPA, took public comment, and prepared their report. Most of the meeting was spent writing and editing sections of the report and then considering the report for the approval. Although the meeting did not proceed exactly according to the times on the attached agenda, the general pattern of the meeting, as represented on the agenda, was followed, except that preparing drafts took longer than expected. On September 12, the Panel approved its draft report conditional upon an opportunity for the panelists to confirm that requested changes had been correctly made. More detailed chronological summaries of each day's events are attached.

Dr. Thomas adjourned the meeting at noon on September 12

Respectfully Submitted: Certified as True:

/ Signed / ***/ Signed /***

Ms. Kathleen White
Designated Federal Official
Environmental Engineering Committee

Dr. Valerie Thomas, Chair

Electronic Attachments

1. Federal Register notice
2. Agenda for the meeting
3. Committee roster
4. Detailed Summaries of September 10, 11 and 12

Paper Attachments

Sign-in Sheets
Preliminary Comments of Individual Panelists
Overheads used by Bill Wood of EPA in his presentation
Overheads used by Kevin Bromberg of SBA Office of Advocacy in his presentation.
Overheads used by Bill Adams of Rio Tinto in his presentation
Mertz, W. 1993. Essential Trace Metals: New Definitions Based on New Paradigms. *Nutrition Reviews* 51(10):287-295. (provided by B. Weiss)
Panel Draft prepared September 10 and distributed on the morning of September 11
Panel Draft prepared and distributed on the afternoon of September 11
Panel Draft distributed on the morning of September 12
Panel Draft forwarded to SAB Executive Committee for consideration

Attachment 1: Federal Register Notice

[Federal Register: August 16, 2002 (Volume 67, Number 159)]
[Notices]
[Page 53584-53585]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr16au02-87]

ENVIRONMENTAL PROTECTION AGENCY
[FRL-7260-5]

EPA Science Advisory Board; Notification of Public Advisory Committee Meeting

Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Metals Assessment Panel of the US EPA Science Advisory Board (SAB) will meet on the dates and times noted below. All times noted are Eastern Daylight Time. All meetings are open to the public, however, seating is limited and available on a first come basis. Important Notice: Documents that are the subject of SAB reviews are normally available from the originating EPA office and are not available from the SAB Office--information concerning availability of documents from the relevant Program Office is included below.

Metals Assessment Panel (MAP)--Meeting Dates

The Metals Assessment Panel of the EPA Science Advisory Board (SAB), will meet September 10-12, 2002 in the Dewey room on the plaza level of the Hilton Crystal City at Ronald Reagan National Airport, 2399 Jefferson Davis Highway, Arlington, VA 22202 (Tel. 703-418-6800). The meeting will begin by 9 a.m. on Tuesday September 10 and adjourn no later than 5 p.m. on Thursday September 12.

Purpose of the Meeting--The EPA Science Advisory Board (SAB, Board) announced in 67 FR 38957-38959, June 6, 2002 that it had been asked to undertake a review of EPA's draft Action Plan for the ``Framework for Metals Assessment and Cross-Agency Guidance for Assessing Metals-Related Hazard and Risk.'' The background, charge, and description of the review documents appear in the above referenced Federal Register notice and are also available at the SAB Web site (<AHREF="http://www.epa.gov/sab">www.epa.gov/sab</A>).

Charge to the Subcommittee--The charge for this review was published in 67 FR 38957-38959, June 6, 2002.

Availability of Review Materials: The review documents and their availability was published in 67 FR 46505-46506, July 15, 2002.

For Further Information--Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments (10 minutes or less) must contact Kathleen White, Designated Federal Officer, EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone (202) 564-4559; FAX (202) 501-0582; or via e-mail at <A HREF="mailto:white.kathleen@epa.gov">white.kathleen@epa.gov</A>. Requests for oral comments must be in writing (e-mail, fax or mail) and received by Kathleen White no later than noon Eastern Daylight Time on Tuesday, September 3.

Providing Oral or Written Comments at SAB Meetings

It is the policy of the EPA Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. Oral Comments: In general, each individual or group requesting an oral presentation at a

face-to-face meeting will be limited to a total time of ten minutes (unless otherwise indicated). For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. Written Comments: Although the SAB accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 25 copies of their comments for public distribution.

General Information--Additional information concerning the EPA Science Advisory Board, its structure, function, and composition, may be found on the
[[Page 53585]]

SAB Web site (<A HREF="http://www.epa.gov/sab">http://www.epa.gov/sab</A>) and in The FY2001 Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564-4533 or via fax at (202) 501-0256. Committee rosters, draft Agendas and meeting calendars are also located on our Web site.

Meeting Access--Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact the DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: August 12, 2002.
A. Robert Flaak,
Acting Deputy Staff Director, EPA Science Advisory Board.
[FR Doc. 02-20872 Filed 8-15-02; 8:45 am]
BILLING CODE 6560-50-P

Attachment 2 Agenda

SCIENCE ADVISORY BOARD - METALS ASSESSMENT PANEL
MEETING
September 10-12, 2002
AGENDA

Hilton Crystal City at Ronald Reagan National Airport,
2399 Jefferson Davis Highway, Arlington, VA 22202 (Tel. 703-418-6800)
in the Dewey room on the plaza level

(Materials relating to this review are posted on the Science Advisory Board Website, *"Metals Assessment Panel"* page at the following URL address: **http://www.epa.gov/sab/metalspanel.html**)

Tuesday September 10, 2002

9:00	Welcome and Opening Remarks	Dr. V. Thomas, chair
9:10	Procedures and Practicalities	Ms. K. White, SAB staff
9:20	Agency Briefings	Dr. Wm. Wood, ORD

10:20 Q&A

10:40 Public Comment

11:20 Consideration of Responses to Individual Charge Questions

11:20 Charge Question #1
11:40 Charge Question #2

12:00 LUNCH

1:20 Charge Question #3
1:40 Charge Question #4
2:00 Charge Question #5
2:20 Charge Question #6
2:40 Charge Question #7
3:00 Charge Question #8

3:20 BREAK

3:40 Executive Summary and Cover Letter

4:00 Identification of Potential Cross-Cutting Issues

4:20 Panel Adjourns to Write and Provide DFO with revised material by 6:00

Wednesday September 11, 2002

9:00 Draft Available - Reading Period
9:30 Discussion of Executive Summary and Cover Letter

Consideration of Responses to Individual Charge Questions for Approval of Content and Recommendations about Tone, Style, etc.

10:30 Charge Question #1
10:40 Charge Question #2
10:50 Charge Question #3
11:00 Charge Question #4
11:10 Charge Question #5
11:20 Charge Question #6
11:30 Charge Question #7
11:40 Charge Question #8

11:50 Writing Session, revisions to DFO by 12:30 sharp

12:30 LUNCH

2:00 Reading Period for Revised Text
2:30 Conditional approval of final text for Question #1-8
3:30 BREAK
4:00 Conditional approval of Executive Summary and Cover Letter
5:00 ADJOURN

Thursday September 12, 2002

9:00 Draft Available - Reading Period

9:30 Confirmation that all requested changes to text have been made

10:30 Chair's Summary of Major Findings and Recommendations

11:00 Opportunity for Agency Response

11:30 Consideration of Full Report for Final Approval

12:00 LUNCH

1:00 Reserved if further time is need to complete and approve report.

TBA BREAK

5:00 Adjourn

Attachment 3 Roster

U.S. Environmental Protection Agency - Science Advisory Board
Metals Assessment Panel*

CHAIR
Dr. Valerie Thomas, Princeton University, Princeton NY
Also Member: Environmental Engineering Committee

OTHER SAB MEMBERS
Dr. Charles A. Pittinger, Cadmus Group Inc, Cincinnati, OH
Member: Ecological Processes and Effects Committee

CONSULTANTS

Dr. Bruce Fowler, Agency for Toxic Substances and Diseases Registry, Atlanta GA

Dr. Andrew Friedland, Dartmouth College, Hanover, NH

Dr. Kim Hayes, University of Michigan, Ann Arbor, MI

Dr. Mary Kay O'Rourke, University of Arizona

Dr. Nga L. Tran, Exponent, Washington, DC

Dr. Bernard Weiss, University of Rochester Medical Center, Rochester, NY

Dr. Herbert L. Windom, Skidaway Institute of Oceanography, Savannah, GA

SCIENCE ADVISORY BOARD STAFF
Ms. Kathleen White, Designated Federal Officer, Washington, DC

Ms. Zisa Lubarov-Walton, Management Assistant, Washington, DC

* Members of this SAB Panel consist of: a) SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees. b) SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue. c) Liaisons: Members of other Federal Advisory Committees who are not Members or Consultants of the Board. d) Federal Experts: The SAB charter precludes Federal employees from being Members of the Board. "Federal Experts" are federal employees who have technical knowledge and expertise relevant to the subject matter under review or study by a particular panel.

ATTACHMENT 4

Detailed Summaries of September 10, 11 and 12

September 10

Attendees

Panel: Drs. Fowler, Friedland, Hayes, O'Rourke, Pittinger, Thomas, Tran Weiss, Windom.

SAB Staff: Kathleen White (DFO for the Metals Assessment Panel), Zisa Lubarov-Walton (MA for the Metals Assessment Panel), Jim Rowe (DFO for the Drinking Water Committee), Sue Shallal (DFO for the Environmental Health Committee), Vanessa Vu (Staff Director)

EPA in Audience: Bill Wood, Kevin Minoli (OGC), Stephen DeVito, Charles DeLos (OW), Marc Stifelman (Region 10), Randy Wentzel, Alec McBride (OSW)

Federal: Kevin Bromberg, SBA

Public: Bill Adams of Rio Tinto, Meredith Preston of BNA, Ann Smith-Reiser of Analytical Services, Jane Luxton of King and Spalding, John Arnett of the Copper& Brass Fabricators Council, Melvin Keener of CRWI, Cheryl Hogue of C&EN, Mario Gamboa of the American Chemistry Council, Sueanne Pfifferling of Pfifferling and Associates, Hugh Morrow of the International Cadmium Association

(When the panel resumed after lunch, there were fewer people in the audience about eight. At 5 p.m. there were five people: SAB's Lubarov-Walton and Vu, Bill Adams, Jane Luxton, and Marc Stifelman)

Dr. Thomas welcomed people to the meeting. Ms. White introduced the SAB Staff present at the meeting. She reviewed the panel formation process, then reminded people of the availability of biosketches and other materials. When an opportunity was given to ask questions about procedures, no one asked any. The DFO said people could ask her privately later. The panel gave brief self-introductions as did the audience.

Technical difficulties led to a delay of presentations until 9:35

EPA's Bill Wood gave the Agency briefing. The SAB staff has requested a set of overheads from Dr. Wood. If he makes them available, they will be found in the FACA file for this meeting.

Wood reviewed the history leading to the review of the draft Action Plan, including the February 20, 2002 Stakeholder Meeting and key recommendations

The Action Plan is EPA's vision for where they are going and how they propose to get there. It has three components. It identifies the key issues about metals that will be addressed in the Framework and associated Guidance, proposes a structure for the Framework, and sets out a process that will culminate in the production of the Framework and Guidance. The intended audience is primarily EPA risk assessors, risk managers and other who perform assessments for the Agency. A secondary audience is the public (including stakeholders) interested in understanding EPA's approach to the assessment of metals.

The Action Plan is not the only EPA document dealing with risk assessments. Risk assessments are carried out in the context of broad Agency guidance on risk assessments. GAO identified EPA as the only federal Agency with risk assessment guidelines that are cross-Agency and not chemical specific. In addition to risk assessment guidelines there are other documents that relate, such as the Quality System, OMB's Information Quality Guidelines. There are also program specific guidances such as Superfund Risk assessment Guidelines (RAQGS) and OW's Human Health Assessment Methodology.

The Framework and Guidance will not replicate these existing guidances but will focus on **What's Different About Assessment of Metals?**

For purposes of discussion EPA is considering three types of assessments: (1) Site-specific Assessment, (2) National Regulatory Assessments, and (3) National Ranking and Characterization Assessments. He indicated that it was challenging to take the science that we know how to apply, to some degree, at site-specific applications and apply it to broader scale assessments. After describing elements needed for each of these kinds of assessments, Wood listed about 20 metals currently of interest to EPA programs, illustrating that many of the same chemicals are of interest to several programs.

In response to a question from Pittinger on the criteria for considering a metal, Wood said that the pragmatic answer is that if a metal is already on a list, it could be considered. He noted EPA has struggled with American Chemical definitions and other sources to defining what metals are, but for now are sticking with existing chemicals on lists.

The Action Plan identifies five major science issues: Chemical Speciation, Bioavailability, Bioaccumulation, Toxicity, and Persistence. EPA does want to know if it has overlooked anything

EPA's goal is to have the Framework by the end of 2003 and Guidance by spring 2004. EPA plans to develop white papers on issues in the Action Plan using a team of an Agency scientist with 2-3 outside scientists for each. The white papers should not be extensive, typically 20-30 pages in length. These would be analogous to the Action Plan – how would you address this issue? After the white papers are available, EPA will

hold a workshop to give them a better idea of how to do the Framework. Wood asked, “Does the Panel think this schedule is too ambitious?”

Wood summarized public comment on the Draft Action Plan, saying there were some suggestions about staging the development of further documents, perhaps postponing organo-metallics, and some importance placed on distinguishing between metals and compounds.

He then reviewed the charge questions, which can be found in the Federal Register, at the SAB website, in the preliminary draft comments for August 29 and in the Subcommittee’s reports.

A question and answer period began at 10:15. Tran asked about the thinking behind keeping health and eco together in the framework. Wood responded that lots of issues are the same in health and eco. However, the tools you have to assess them can be quite different. EPA would like to hear SAB’s thoughts on whether to keep the two together or separate them. EPA has an ecological risk assessment framework; we could do one tailored to metals. Priority setting processes tend to lump rather than split. Perhaps, to make the metals guidance applicable at the priority setting level, it might be easier to lump.

Pittinger observed that, from the time lines presented, it appears that the Action Plan was developed after the Stakeholder Meeting. Wood agreed.

When asked why EPA proposes both a Framework and a Guidance when there seems to be considerable overlap between them, Wood responded that the Framework applies to a number of different regulatory applications and should be flexible. The more specific detailed guidance for a narrower set of applications would be in the Guidance. The Framework is needed to support development of the Guidance. The Guidance could also be updated more often as experience in applications develops.

Fowler asked whether EPA planned to address only the non-organo-metallic forms. Wood indicated that EPA had not yet decided and would wait for both the Panel's recommendations and Workshop input before deciding. At this time, EPA is leaning towards excluding organo-metallics from this series of documents. Fowler thinks thorough discussion is needed because EPA might end up with more trouble by eliminating the organo-metals.

Fowler also thinks Action Plan needs to address mixtures, even by bringing language in from Chemical mixtures document. Wood asked for input on how metals can be looked at, even in a different way . . . data bases to look at etc. Fowler thinks the conversion of metals and organo-metals has led to clear concepts. Depending on the organism, there is the issue Weiss raised about nutritional elements which leads to consideration of populations at risk. EPA should indicate an awareness of this even if it can’t go into it in depth.

Weiss is still concerned about the sequence of how the Framework is supposed to be defined first and then the Guidance document. He thinks EPA needs to consider how the Guidance document will be used before it can develop the Framework.

Thomas observed that the organizing principles were confused. Wood responded that the Framework is intended to be broad and give people and idea of how some things will be done. The Framework will be an expansion of the Action Plan and include some recommendations on methods. Maybe, if we are smart enough, it could include a decision tree. Then there is the practical aspect of how do you apply this to decide whether a metal ought to be on a list. What do you do when you don't know the form of the release, etc. and stay true to the science?

Thomas understands that the Framework will address how to assess bioaccumulation, toxicity, etc. for risk assessment. Wood said the Framework will lay out a range of possibilities for how to address the issues. Thomas says this description changes her idea – the Framework is not how to do assessment of metals from soup to nuts. The Guidance is how to do hazard ranking and prioritization of metals in this PBT context. Wood observed that it doesn't have to be PBT, it is an expanded Framework.

Speaking for Agency, Vu noted that the Agency's thought was to develop a Framework that would articulate the key science issues when EPA wants to conduct an assessment of metals and metals compounds – a very generic living document identifying science principles. On a parallel track the Agency would develop a document on prioritization of metals and metal compounds what kinds of data and methods should you do this. It seems like the Agency is moving generic to specific while Weiss may be from the more specific to the more general.

Then, speaking as SAB Director, Vu said she is generally interested in having SAB review groups provide advice on the needs of the Agency.

O'Rourke has struggled to organize this material in her own mind. She now understands that EPA is asking the Panel to look at the issues that need to go into the Framework to see if there is a complete list. Because she doesn't have a paradigm for what the Framework has to do to be able to tell EPA what is missing, she is somewhat at a loss. Wood responded that one paradigm is the risk assessment paradigm. Whether a different paradigm is needed for metals might be a different question. The panel might need to think hard about how the risk assessment paradigm works for metals. Perhaps questions like essentiality would influence the dose-response approach. EPA is trying to think about issues in the existing risk assessment

In response to O' Rourke's question, "Do you want to go as broad as the Agent-Environment-Host paradigm? Wood responded that might be a little broad. For example, take the issue of Agent – it could be metal elements, compounds, alloys. A problem formulations step helps, "What am I dealing with here?" Someone observed that a lot of the priority setting schemes ARE broad.

Windom noted that there is history on organic compounds which might cause EPA to push metals into the same approach. However, metals are different – they occur naturally and humans just redistribute them. A major issue in evaluating hazards and risks of metals is what the background is to begin with. This is in the Action Plan, but seems like EPA is struggling with it. The focus on speciation seems to come from the organics mind set – EPA is looking at a particular compound and wants to know how it behaves, so EPA starts looking at the most toxic compounds the metals can form. He thinks the focus should be on the environment and what compounds can form in that environment. EPA needs to give more consideration to the natural environment and especially any metals problems that are new to nature. Weiss gave as an example, a problem in Canada when they built huge dams to supply power to NY state. The dam building flooded a lot of vegetation that accelerated the transformation of mercury to methyl mercury.

Windom added that there are microbial processes that can change the transformation. Speciation IS important, understanding the processes that cause the speciation and transformation is more important. It is part of environmental chemistry.

Wentzel responded that EPA staff recognizes that the physical, chemical, and biological parameters control speciation. If it if is not called out adequately in the document, it should be.

Hayes understood speciation discussion to be broader (environmental chemistry) He had a concern about the structure, in particular the Tiered Approach. He understands site-specific, national regulatory, and ranking. As long as it is clear that this is in the context of risk assessment things are clearer. If it is risk assessment and problem formulation, then EPA probably assumed that this was a given, but it took him a while to catch on. Hayes did not cite or quote from an upcoming NRC document, nor did he provide anything specific about its content because it has not been approved for release. However, he did suggest that the following NRC report might be of interest to the Agency and others when available -- "Bioavailability of Contaminants in Soils and Sediments," Water Science and Technology Board, Division on Earth and Life Studies, National Research Councils, National Academy Press, Washington D.C., Richard G. Luthy, Stanford University, Chair of Committee on Bioavailability of Contaminants in Soils and Sediments.

Friedland agreed with Windom that the current document is organo-centric. He thinks that there is a cost to this and suggests EPA write primarily about metals. As to whether EPA has identified the major scientific issues, perhaps persistence is not relevant, the issues seem to be addressed in speciation. An issue that several people have brought up is synergisms. The document on chemical mixtures appear to only deal with human health. Even if other documents exist, the major issues ought to be mentioned in the Action Plan.

At 10:45, Kevin Bromberg of SBA provided public comment. The reader should refer to his overheads, attached. He works in SBA's Office of Advocacy. It includes a

tax person, a labor policy person and himself on Environmental Policy. He observed that the Panel has been very attentive to complex and time consuming issues and had operated with an open and transparent process. The panel has worked hard.

Key Questions are:

What is the State of the Science of PBT's and Metals at EPA?

What is the State of Science of PBTs and Metals Outside of EPA?
Small business spend 60%more per employee to comply with federal regulations.
Science based regulations allow formulation of better rules at less cost, so science is their friend.

Why is SBA here? It's not a secret that there was a TRI lead rule in the last Administration that involved PBT. We were part of the interagency review of the draft final rule.

EPA started out believing metals and organics can be treated alike. The first PBT rule (1999) announced that metals can be treated like organics for the purpose of classifying metals as PBTs. This rule did not discuss bioaccumulation. The 1998 OECD document says that "care" should be used in addressing metals and PBT characterization because metals are different in several ways. Two major factors they raised were bioavailability and bioaccumulation.

The 1999 Generic PBT Rule did not address the issue with care, eliminated bioavailability as an issue by assuming that all metals can be bioavailable under some circumstances, and failed to address bioaccumulation at all.

2001 TRI/Lead Rule

EPA claimed that the same PBT methodology can be applied to metals and organics, but provided no literature support for the proposition.

No peer review was performed as required by EPA procedures

The Lead rule preamble recognized that peer review wasn't done and said EPA will seek review after promulgation. This SAB review is part of the peer review process for this rule.

The 2001 Report of Inorganics Working Group to Environment Canada found that the approach for synthetic organics is not applicable to inorganics.
BCF/BAF factors generally should not be used for inorganics.
Adams explained BCF and BAF as relating concentration in tissues/concentration in the water.
BCFs in the lab are based on measurements made where the exposure is only in water, not the food.

BAFs are developed in the field, incorporates food and usually deals with real world exposure where you don't know what was in the food.
At the February 20meeting on the metals framework, all the speakers were critical of the EPA PBT hazard ranking approach for metals.

The Draft MAP recognizes some aspects of the controversy but some inconsistencies remain.
It doesn't make a lot of sense to reformulate the Action Plan because the action has moved to the Framework and Guidance. However, the criticism of the Action Plan isn't wasted, it will just benefit EPA in a different place.

He suggests that the SAB should be briefed on PBT/TRI and RCRA Waste Minimization Prioritization Tool because these are two good examples of hazard ranking schemes of metals. Bromberg later noted that there is a question about at what concentrations BAF/BCF measurements should be made and in which species. By reviewing how EPA applied the hazard ranking scheme in these two examples the SAB could better advise EPA on how to come up with a framework. He said if one doesn't learn from the past, you may repeat the errors of the past.

He knows Panel has received public comments on MAP and knows at least some panelists have read them (because of their writings) However, he wanted to highlight some of the points for the panel that were not addressed in the current response to the charges These points should be added to the response for EPA to review. (See his overheads)

SAB should comment on these Hazard/Risk Ranking schemes as part of the Framework review.
He thinks the ecological and human should be separated and would recommend doing ecological first.

Conclusions:
The national hazard risk ranking schemes should not use BAF/BCF factors.

The SAB should use public comment on the Action Plan to supplement current discussion of charges.

The SAB should provide advice on EPA national hazard risk ranking schemes.

The Panel had no questions for Mr. Bromberg.

At 11:20 Bill Adams of Rio Tinto provided public comment. The reader should refer to his overheads, attached.

Having a working understanding of risk assessment at most works against us, because the situation with metals is more fundamental. He briefly summarized a number of ongoing activities on screening, ranking and classification of inorganic

substances. Because bioaccumulation is important, we need another approach because BAF/BCF doesn't work very well. In the aquatic environment (which is where most international agreements have focused due to the state of the science), if you consider aquatic dependent terrestrial wildlife and look at feeding studies you can get a sense of wildlife sensitivity to metals. Methyl mercury and selenium are bad actors with thresholds of 5. Chrome 6 is 22, Arsenic 43, Zinc over 800.

He agrees persistency does not apply and asked what does allow you to discriminate between one substance and another? The underlying issue is the evaluation of duration of exposure. Maybe "persistence is a property of a metal whereby it remains bioavailable in some form" Naraganset did a series of experiments in mesocosms placed in a marine environment, where half-lives (a measure of presence in the water column) are small, the metals have sorbed to particles or algae. These processes dominate in large lakes and oceans. Looking for a simple assessment tool to separate metals out, ecologists used a model to predict behavior in a standard water and introduce a fixed amount of metal and calculate the portion of free metal ion (which is the dominant toxic form). The answers vary by orders of magnitude.
Using a similar approach and adding interaction with suspended solids, ecologists tried for something like a persistency index for freshwater which integrates suspended solid, free metal ion concentration, and something else. The range is 11 orders of magnitude with bad actors at the top of the list, just like you'd expect.

This is still taking the environment one slice at the time. We aren't and a Unit World Model yet. He has a concept for it that deals with the relationship between dissolved and particulate, DOC and POC, diffusion, settling, aerobic and anaerobic processes, burial, and more. If you were to use this approach, you'd have to think about what part of the environment you really want to concentrate on – sediments, water column, etc. But we aren't there yet.

One might ask, "Why go through this whole exercise where there is a limited number of metals and we might study them all before the model is ready?"
He referenced the Mercury Report to Congress as the most detailed study of a metal. What if you asked, "What's the next metals we should study like this?" There are similar questions in the international setting.

Windom observed that environmental chemists and geochemists do this kind of thing all the time because there are so many complexities that are not easily amenable to the numeric model. Any good geochemist could sit down with this model and analyze a single metal. The thing with mercury is the natural background are so near the level at which there can be biological effects, that's why he thinks natural background and redistribution and inventory of releases is important.

Thomas asked a question on behalf of organo-centrism. She liked the context of Adams' talk and the way he went through the approaches. In all of those, at the end of the day, EPA has to be able to take its approach and integrated it with organics. Somehow, in the end, EPA has to be able to do a hazard ranking in the same

framework. Adams understands, has engaged this debate at some length. Internationally, people are still striving for this, but it has not been a successful effort. It has meant leaving some of the science out . . . . unless you just look at toxicity.

Windom asked, “Why is a joint ranking important?”” and Thomas responded that she imagines OSW might ask, “which wastes should be our priorities for minimization?” This might not be a quantitative ranking. Some of what she’s heard is that EPA tried it before, it wasn’t very satisfactory, and is going towards a Framework that will allow EPA to make progress on ranking. O’Rourke reminded the Panel that, metals aren’t organics. Essentiality is an issue. The protective qualities of selenium are a hot issue in the cancer issues right now. The poison is in the dose. Metals are very complex because of essentiality. Hard to see how to rank for one set of needs while not conflicting with others.

Thomas noted that the Guidance which EPA is developing will be about ranking the hazards of metals. Sometimes in the context of pollutants or stressors that aren’t metals as well as metals. Adams responded that various program offices have already identified hazardous metals for water quality criteria, HAPS, and waste min, so the Agency has already set some metals priority. The EU does not see the PBT approach as successful for metals, but they still have to set priorities. He doesn’t know if the EU will compare organics and metals.

Vu speaking for the Agency, observed that this Panel is not quite clear about what they have been asked to provide advice on. EPA is not interested in asking the SAB to review the PBT tool, nor the Waste Min Prioritization Tool. EPA recognizes the limitations of these tools to metals and wishes to recognize the complexities. EPA needs to know if the plan is a sound one.

Vu as Staff Director asked Panel to focus on the Action Plan itself without focusing on the Framework and Guidance.

Thomas asked the panel whether there were needs for further clarification. O’Rourke understands what Vu said but recognizes that the Panel will slop over because that’s how they operate.

Vu would like Panel to focus on the charge, but said it was OK to address other issues.

Tran asked Adams why there is little mention of surveillance and monitoring data. Adams first said to Vu that he hadn’t meant to get the Panel down the wrong path, then responded that, as you move from ranking to the first screening level risk assessment, you need the surveillance and monitoring data. It’s not usually used in the approaches he discussed, but sometimes is.

Wood noted that PBT frameworks and International approaches are all very broad in nature. It is important NOT just to look at the aquatic ecosystem and human

exposure through the aquatic ecosystem. But the question arises in the framework . . . what about other ecosystems and human exposures. You want to be careful that these simplified schemes don't lead you someplace you don't want to be.

Pittinger underscored the point regarding the significance of hazard in risk. On conference calls panelists noted the Action Plan doesn't clearly distinguish between hazard and risk. Many people view hazard assessment as more conservative than risk assessment. In his experience, this is not always the case. Therefore, there is a danger to the hazard approach. Gave a consumer product example – hazard is low but exposure is high so that risk may be high.

After the break, Thomas and Panel spoke about the writing of the report. Thomas said the Panel will proceed charge question by charge question, preliminarily keeping the leads. The Panel will identify the key points to the response on each question. Then the lead authors will revise the responses to all charge questions so that revised text can be distributed in the morning. In addition to answering all charge questions, the Panel should think about what should be in Executive Summary, which she will draft. The Panel will look at everything again in the morning

CHARGE QUESTION # 1

Please comment on the soundness of the proposed organizing principles suggested by the public that are reflected in the draft Action Plan for the ``Framework for Metals Assessment and Cross-Agency Guidance for Assessing Metals-Related Hazard and Risk." (The proposed organizing principles, listed in section 1 of the draft Action Plan, include the following: providing a basis for identifying and prioritizing among metals, metal alloys and other metal compounds with respect to hazard and risk, use of sound science, use of a tiered approach, recognition of the influence of bioavailability on toxicity, and initially focus on hazard assessment as a screening tool.)

Fowler didn't receive any comments from the panelists, so he thinks the real question for this question is what level of detail. Thomas next called on the rest of the team for this question. Pittinger asked whether the term "sound science" captures "current science"It needs to be current and dynamic. Secondly, he doesn't think hazard assessment should always be the first focus. As Hayes noted, exposure is also very important. Otherwise he agrees with what is there. Fowler agreed and asked, "Hazard to whom or what?" He proposes that the Panel decide whether to recommend EPA have a generic all-encompassing document or separate the human health and ecological assessment right now.

O'Rourke does not have a paradigm to function with, therefore determining what the issues are, much less prioritizing them, becomes problematic for her. Therefore she wrote something that backs up and takes a very broad paradigm (Agent, Environment, Host) In that case, the issues are unique to each of those three issues. She found she wrote a chemi-centric universe and she found that there was a lot about agents and environments, but very very little about hosts. Until she had a construct, it was hard for

her to see what was missing. Using the A-E-H paradigm, she sees a log that's missing, but still has trouble setting priorities.

Then Thomas had the panelists ask questions

Tran had written about separating health and eco. Based on what she heard this morning, there seem to be no advantages to keeping them together. The same words can mean different things in eco and health risk assessment jargon which can lead to confusion. She thinks separating them is helpful.

After struggling with this document, Thomas thinks the organizing principles are not right and are causing Panel and EPA some confusion. She imagines the organizing principles are what is EPA going to do and how EPA is going to do it. It is not clear from the draft Action Plan what EPA will do. It is written as a framework for a risk assessment of metals, but it sounds like EPA is interested in other things.

Risk assessment involves a lot of issues the Panel knows EPA knows about which are not in the Action plan such as exposure and special populations. She now understands the actual organizing principle is how to deal with the five issues of speciation, bioaccumulation, etc. AND/OR how to do a hazard ranking that includes metals.

She suggests the Panel recommend that EPA narrow and clarify what is doing. Fowler remarked that the Panel has been around this several times. He sees it as a level of detail question. Thomas does not see it as a level of detail question. If you are doing risk assessment of metals, sometimes BAF/BCF are essential and sometimes they don't come into play at all. It's not just a matter of detail, but what the document is called and what's in it. Fowler thinks this is a living generic guidance document. EPA doesn't need all the details and the Panel can't imagine them all anyway. He'd like the Agency to restate what they want in five sentences or less.

Speaking for the Agency, Vu observed that the Agency has developed guidance for ecological and human health assessment. Other SAB panels have urged greater integration. On page 5, the Action Plan gives the organizing principles which list the scope of the Framework. If Panel wants to talk about these points, that could be helpful. Question #1 doesn't deal with the details, that's the next question. Question #1 is about the appropriate organizing principles.

Thomas suggested that, as the organizing principle, what the Framework is for and what the Guidance is for is important. She suggests they aren't for the risk assessment of metals, but for narrower issues. She thinks this would keep EPA from having to include everything here. Thomas thinks there is confusion about what EPA is saying. EPA doesn't want to redo everything about every metals risk assessment, but change some things.

Windom sees the Action Plan as an attempt to provide cross-Agency advice on what to consider in addressing metals. He thinks the organizing principles are pretty straight-forward (the Panel might want to emphasize Pittinger's point about currency) He thinks Panel should address human v ecological. He thinks both can be accommodated in a single framework because humans are in the ecosystem. The things he's most concerned about are what might not be there. One is variability in the natural environment. If the Panel reads too much detail into the first question, it will go round and round.

Hayes said that you could argue for or against separation of human health and eco. He agrees with Windom that there are benefits to including both in the Framework but may need separate documents for Guidance. He was troubled by the lack of emphasis on risk, but now thinks that results from their emphasis on what's different about metals. He observed that you can see the outline for the Framework has many more details than the Action Plan.

Tran agrees that the separation is most important at the Guidance Level. If you look at the Framework outline you can see that the differences in approaches begin to emerge. Friedland advocates that the Framework be one for human and ecosystem health. Guidance for characterizing and ranking metals could be separated.

Friedland's second comment was a plea for brevity. Question #1 is very straight forward. The Panel members may have spilled their guts, but each Panelist knows how to write an abstract. While it will be intellectually rewarding to continue on the current path, if the Panel wants to finish and be useful, it needs to be brief. In some cases the Panel will have to distill what the writing teams have already written. Fowler agrees brevity is a virtue in this business.

O'Rourke, returning to sound science and noted that there may be sound science for certain entities, but not others.

Human health and eco should be combined at Framework Level, but can be separated at the Guidance level as long as the Framework is clear. Sound science should use most currently available science and leave room for new science to come in. Instead of the initial focus on hazard assessment, EPA should clearly distinguish of hazard and risk assessment and apply them on a context specific basis.

CHARGE QUESTION #2

Are the issues raised in the Action Plan--chemical speciation, bioavailability, bioaccumulation, persistence, and toxicity--the major issues of concern for improving EPA's scientific assessments of the hazards and risks of metals?

Hayes summarized this as follows. Mainly the five major issues are properly listed. There is some question over the utility of bioaccumulation and persistence, but they are still a worthy starting point for the framework. In the present organic approach to assessment, speciation, bioavailability and toxicity information are important.

Whether they are framed properly or not can be considered separately.

Friedland agrees these are major issues, but persistence in the case of metals could be considered differently than for organics so that differences between metals can be better discerned. Secondly as Hayes has written, synergy could be considered more prominently.

Windom observed that in 35 years of doing research on metals he has never heard persistence used to discuss metals. The Action Plan is organo-centric and EPA needs to get rid of it. Also, too much prominence is given to speciation when it is environmental chemistry that you want to know about. It is more intellectually honest to talk about environmental chemistry than speciation.

Thomas asked Windom to lead on Q#2 to incorporate everyone's input.

O'Rourke said Windom just took what they thought should be global in the framework and focused it down. Windom and Weiss disagree. Weiss says, don't organize the plan like a series of snapshots, but show the dynamics. Friedland thought whether speciation includes the larger concepts of environmental chemistry or not was semantics. He thinks speciation gets to the issue of where metals present risks. He'll work with Windom

Thomas thought that persistence seems to have gotten into the Action Plan because of the PBT framework. Windom thinks prevalence of a particular species and its bioavailability is what matters. Pittinger thinks there may be a parallel to organo-centrism for PBT. There was a discussion of Profile or Prevalence, Bioavailability rather than Bioaccumulation, and Transport. He doesn't see anything about exposure and the ability of some metals to transport.

Windom observed that speciation doesn't just have to do with what's most toxic, but also about what is most mobile. Someone suggested that there could be a PBT for metals which is different than the PBT for organics. Windom thinks this may confuse rather than help.

Windom summarized saying that, in general the five issues are important, with the exception of persistence which is really not applicable to metals. Perhaps persistence and chemical speciation could be d dealt with better by an umbrella issue of environmental chemistry which would address the formation and . . . of species which are toxic and easily transport.

CHARGE QUESTION # 3

Has EPA adequately characterized the issues and do the summaries adequately capture the key scientific uncertainties that will need to be addressed by the Framework and the Guidance?

Hayes said that the issues raised are important, but perhaps not all-inclusive. More details could be provided in the Framework than in the Action Plan. For example, Issue Summary 2.2.5 -- as far as he could tell there was virtually no information on background levels of metals. So, it was correctly identified as important but not adequately characterized. Another example is "lack of data . . . gut absorption . . . what methods?" The Agency didn't address the models, available data, speciation issues. So, again, the questions EPA asked are important, but the discussions are lacking.

The discussion on bioaccumulation is an exception. In that case the summary followed the discussion and the discussion supported the summary.

His answer to Question #3 is, basically, no. Nevertheless, he agrees that these issues are important. He doesn't think the Panel should necessarily recommend that EPA put this information in the Action Plan. It might make more sense to put it in the Framework.

Friedland suggested that perhaps the longer comments can be passed on to EPA without their having to be in the body of the report.

The Panel discussed Quality Assurance and uncertainty. and whether the issues of synergism and mixtures should be addressed here. In relation to uncertainties and the Framework document, Windom was concerned about uncertainty about the natural variability of metals in the environment. Metals levels as they exist may be due to natural processes. The other uncertainty he wished to raise relates to taking laboratory bioassay results and models and extrapolating them to real settings. Simultaneously Extracted Metals/AVS method is often used by the uninitiated in situations where it does not apply. A blind faith in things as established by laboratory work and models is not warranted.

Friedland observes that some of the same concerns are popping up in more than one response. Mixtures and synergisms, for example, doesn't have to appear several times. So we can think about where best to put them. Thomas thinks that can be dealt with in 2,5 and 8. Tran noted that the questions themselves are redundant.

Weiss was concerned about different media and bringing them together. FQPA requires all sources be considered and it doesn't seem to him that need will be adequately addressed by the Framework.

Thomas is hearing so far that the answer to Question #3 is no, but the Panel seems less sure how and where EPA should address it. She asked Hayes for a short summary statement of the views of the panel on Question #3. She doesn't want to lose his detailed suggestions. One approach might be a summary of the panel's thinking with a second piece that is his final revised version of his detailed question.

Hayes asked whether the Panelists felt that the summary issues were capturing, in a more specific sense, the key science issues. Wishing to help Dr. Hayes, Vu

commented that Question #2 only asked whether all the relevant issues were addressed. Question #3 asks whether they were adequately addressed. She understood Dr. Hayes to say that the summary section does not fully reflect the document and that he recommends that the effort be spent on strengthening the Framework rather than rewriting the Action Plan.

O'Rourke thinks this is an editorial problem. If you clean up the editorial problem, some of the rest will go away. She asked Hayes whether he saw the five issues (bio, bio, persistence, speciation, toxicity) Yes. Aside from synergisms/mixtures these are the issues that should be included.

Weiss said his impression is that the question of speciation did not adequately address environmental dynamics as Windom had pointed out. Pittinger seconded Weiss's comment, especially relating to transport. Hayes thought persistence was not adequately characterized and should be removed. O'Rourke understands everyone else things environmental incorporates human health, but she's used to thinking of it as external to any organism. She wonders if all readers will understand and connect that way. Windom thinks they might need to put in some language up front so people will be considered in the word "environment" Tran thinks we need to be very clear about the receptors because they drive the assessment and the data needs.

Thomas said that the intent was that EPA had identified five issues which, with some caveats, the Panel thinks are the right issues. As EPA moves forward, does it have the right science issues and uncertainties in mind? This is different than questions of document clarity. For example, is there something missing from these five issues that should be included?

Weiss think that what's left out is the process by which these things occur – what Windom means by environmental chemistry. Pittinger is not sure we can call these five the right issues if before lunch we said persistence did not belong in the mix.

CHARGE QUESTION # 4

Can the SAB suggest priorities within the list of issues based on (a) the potential impact on the assessment of risk or hazard and (b) the state-of-the-science and the feasibility of developing guidance in the near term?

O'Rourke developed a paradigm she could stick the question into. O'Rourke noted Tran suggested it would be useful to think about regulatory purposes. Then O'Rourke thought about how one would set priorities. Of the five issues, thinking biostatistically, which are independent, which are dependent, and how do they relate to one another. From her perspective chemical speciation is the only independent issue, which would subsume persistence/stability if retained. Toxicity depends on the species. Bioavailability was very attractive because it depends on all of the others and is influenced by the host. Therefore, she thinks bioavailability it best to rank on because it is integrated.

When she considered state-of-the science and sorted out which variables she would put under hazard assessment and toxicity, she thought about them by type of environment and organism groups as a way to decide whether the data bases are adequate. In other words, you would think about what data is available for an issue in a terrestrial environment for a defined group of organisms.

Tran added, because we have so much information on aquatics, this might be used as a pilot case and see what falls out as drivers. Pittinger finds O'Rourke's paradigm helpful and agrees speciation is the fundamental independent variable, but wonders about ranking persistence if we are going to recommend it be dropped. Finally, and this may apply more to Guidance, context of use and exposure are more important than these inherent properties of a metal.

Fowler agrees.

Thomas noted that it is a yes/no question. Can we suggest priorities? Pittinger and Fowler think it is difficult to suggest priorities at this global level. Pittinger also thinks he would assess priorities difficult in hazard assessment than for risk assessment Weiss would always rank toxicity first and agrees it is context dependent.

Speaking for the Agency, Vu noted the Panel may not have read the question the way the Agency intended. This question asks, if EPA were to develop Guidance, given what we know about these issues, their importance, and the state-of-science . . . which issues should EPA work on first. The question is not about ranking the issues for importance in risk or hazard assessment.

Thomas asked if people had a different response.

Weiss thinks it is still scenario dependent.

Friedland asked whether the Panel was saying there was no way to do this Could we say that because of more knowledge, we are closer to being able to provide Guidance than for other issues. Thomas indicated that EPA could lean more heavily on the elements which are better understood. Friedland gave Hamilton's talk (summarized in minutes of the August 15, 2002 Metals Assessment Panel conference call) as an example. Hayes referenced a paper he reviewed that suggested bioavailability is not well understood, but could have a big impact if better understood and observed that again it gets back to the scenario. If we have the context, we can tell you what we know the most about

Fowler said the Panel was having trouble with one size fits all.

Pittinger thought it might be able to hypothesize a number of typical scenarios and attempt a cross-matrix kind of approach. O'Rourke tried something like this and found she could not think of a single place where there was enough known at that level. Friedland also mentioned that, at that point, the Panel would be doing the risk

assessment and referenced the IED report. He would like to be able to rank beyond a single scenario. Toxicity, for example, can one say that the science is well developed and . . . EPA is working towards a Framework for Metals Assessment, not a metals scenario.

Hayes thought that speciation and bioavailability would be high on his list. It is already reducing cost of clean up at some sites.

Tran asked Friedland whether he could rank without context. Friedland agreed with Hayes about speciation and bioavailability.. He doesn't see it as in a vacuum – it is metals, in terrestrial and aquatic systems He votes for 1, 2, and 3 speciation, bioavailability and toxicity -- maybe not toxicity.

Thomas thinks that EPA is presumably working on toxic metals. If it is going to chose or prioritize, should it work more on speciation (or environmental chemistry), bioavailability, or what.

Weiss noted that toxicity is what drives it. Friedland says toxicity as a driver isn't the issue. Thomas noted that toxicity isn't really in the document. Friedland said if we are all agreed speciation and bioavailability are the important issues, we've done something useful.. Hayes thinks toxicity is important, but better known. Fowler said "what do you mean, toxic?" Dead? Chronic low level effects? Fowler doesn't want to give EPA advice that will lead to blind alleys. Friedland noted, that EPA makes decisions anyway and asked whether some guidance is better than none. Fowler thinks this may not be the panel to make research priority decisions. Windom, who serves on BOSC, thinks there are three primary issues -- bioavailability, toxicity and environmental chemistry (speciation). Basically this covers how toxic is it and how does it behave in the environment. Bioaccumulation isn't going to be important for national assessments.

O'Rourke also asked herself where are the greatest uncertainties. Many environmental chemistry questions are measurable. The uncertainties in the measurements of these other components gather into bioavailability. Windom noted the more complex the system you are trying to model, the greater the uncertainty.

Pittinger senses there are some differences in semantics. He sees speciation and bioavailability as chemical and biological influences on risk. Friedland's proposal to list speciation and bioavailability as priorities was interesting. Pittinger would agree with the caveat of hazard assessment, but for risk assessment would need some element of exposure.

Thomas is not hearing a resounding yes for MAP suggesting priorities for EPA.; The Panel will cycle through this one more time tomorrow. Windom thinks MAP can avoid the issue by saying priorities will be dictated by breakthroughs in the science. EPA should go where the science leads them.

CHARGE QUESTION # 5

Are there specific recommendations for the Framework or for the ``Guidance for Characterization and Ranking of Metals" (including methods and models) for addressing these issues that are not captured by EPA's Action Plan?

Tran led the discussion (see the written response the question #6 distributed before the meeting). Fowler was content with her summary and Hayes indicated his points had been addressed.

Pittinger noted Tran's point on clarity between human and ecological receptors could be addressed under Question #7. Fowler and Weiss had no further comments. Thomas thinks that things like NHANES were not included on purpose because this is NOT a general risk assessment of metals, but a document focusing on the five issues for metals. The Action Plan is not everything you want to know about Metals Risk Assessment.

Because the Action Plan is muddled about this, the Panel keeps going back and forth over other issues that need to be covered for a comprehensive risk assessment. On the one hand, EPA does need to include more to do a risk assessment, on the other hand, EPA did not intend to address these questions in the Action Plan. Pittinger said this is also true for hazard v risk assessment.

Speaking for the Agency, Vu observed that the Panel has gone back and forth on this issue. This morning Wood explained where the Agency wants to go. EPA has generic guidance on stressors, exposure, different endpoints. They are generic guidance for chemicals. Now the question is because metals are different from chemicals, does the Agency need documents on metals assessments alone? If so, can those documents be just about what is unique to metals and supplement with the generic guidance. Perhaps the Panel wants to say, "EPA step away from the generic guidance and do separate comprehensive guidance for metals," perhaps not.

Addressing Question #5, Vu asked, "Given that the stakeholders believe models and methods should be explored further, does the Panel want to recommend any to the EPA?"

O'Rourke says you would do an exposure assessment on any stressor, so what would be different about doing one on a metal? She sees essentiality as the key difference about metals. There are no naturally made PCBs. Windom agrees. There is a parallel to the ecology side. NOAA has status and trend data sets that help establish what natural variability is in certain species.

Pittinger does not agree that the Action Plan should focus just on what's different about metals.

CHARGE QUESTION # 6

Please comment on the feasibility of the proposed process for drafting the Framework and the Guidance. Will the timeline allow for the scientific issues to be adequately

addressed? Are the measures being taken to involve the scientific community and the public adequate?

Weiss led the discussion, dividing the question into the problem of translating the Action Plan to the Framework and the other to communication. Taking the first, first, if I were a risk assessor and said, "What do I do?" Will the Guidance document actually help me?

Speaking for the Agency, Vu responded that she sees communication as different from the intent of the Framework which is for experienced risk assessors. Charge Question 6 relates to the time line for development of the Framework and Guidance. The proposed Metals Framework should be at a similar level to the Ecological Risk Framework.

Weiss found the Action Plan too generic and too vague to communicate clearly. He doesn't think EPA should be trapped in the same practice of writing white papers. Shouldn't EPA be trying to reach out to a wider audience? The document is very conventional in terms of communication.

Weiss is still not sure the target audience is properly served by the document. And he thinks the conventional communication approach is inadequate. He referenced the SAB's IED document. Just saying, "We'll put up a website," isn't enough for him. He wants to know more about how you will include the broad spectrum of the science public, not just the stakeholders. Maybe this is too complex and deep a question for EPA to resolve with this scheme, but it needs to be done sometime. His advice would be to use what we have available to do community surveys, for example, to determine the information the public has about metals. There are two audiences – EPA and interested stakeholders, the general scientific public is one and the public at large is the other.

Windom thought about how fast EPA wants to do this. The primary audience is EPA risk assessors but, ultimately for risk assessors to be successful they have to answer to the public. So, two things are important. There should be more buy in on the issues from the scientific community. Workshops are one way to get that. Getting buy in from the regions is more difficult. For example, heavily impacted areas like Chesapeake Bay have different issues than what is found in his region. Regions may have different issues about what's important. Some parts might want to emphasize predictive models, for example.

Friedland is sympathetic to comments of Weiss and Windom but thinks their comments are much broader than just this review. Hayes doesn't have a strong opinion about whether a decision tree would be better than a Framework based on a risk assessment approach. Even if the Framework process is bureaucratic, it may be valuable.

Weiss observed that the Guidance document helps define what should be in the Framework so they should be closely coordinated. Hayes looked at the Eco Risk Framework and thought he could buy into that kind of approach. Weiss still thinks the two should be done in a coordinated way. O'Rourke asked if Weiss's key point is that "all the usual suspects" work together at regular intervals.

Thomas thinks that the Guidance will be about ranking hazards of metals. That could be a controversial document about which there will be a lot of public discussion. Whereas the Framework is more vanilla. If she is right, they will need a LOT of public input on that guidance, but not before.

Fowler hears Weiss saying the issue is who is the audience – EPA risk assessors and general public. In terms of communications . . . a lot of scientific organizations now ask for BOTH a lay abstract and a technical abstract. If SAB helps EPA get the science right, then it is an editorial issue to create the lay document. Weiss meant something larger. He is also still disturbed by the conjunction of the Framework and Guidance.

Stifelman and Vu (speaking for the Agency) reported that the Framework and Guidance are on parallel tracks with intermittent coordination. Vu hears Weiss suggest a novel way of doing business, but—particularly when you deal with perceived risk – it might be helpful to get early lay input as well as scientific input.

O'Rourke indicated that the feedback lines are missing from the Figure which shows the development of the Framework and Guidance. (Figure 1) Pittinger spoke of the Ecological Risk Framework and suggested tweaking the figure on Page 4 to show what would be different about doing it for metals. He then asked Weiss whether this would be like what Weiss intended by a decision tree. Weiss said he'd think about it. Tran brought up questions of communication with whom and mentioned states and other major parts of the Federal family. She does not recall USDA and FDA represented and they should be because of the essentiality. Who does EPA need to talk to bring forth these issues?

CHARGE QUESTION # 7

Please comment on the outline for the Framework and the description of the Guidance. Is it clear and all-inclusive?

Pittinger finds the Tiered approach based on regulatory function is not an exact match to a Tiered approach based on science. He questions whether this is a good approach. He thinks a tiered risk assessment approach could be applied to each of the regulatory functions. He asks if there is a logical and rational gradation in the amount of data and uncertainty needed for the different regulatory applications.

He also commented on the need to incorporate uses, speciation and context into the ranking exercise. The Panel can't say anything about the clarity and inclusiveness of the Guidance based on the little bit that's in this Action Plan. And that description is not clear and all inclusive because of hazard and risk are muddled.

Other issues raised in discussion were:
Persistence should be dropped
Metals mixture
Distinguishing eco and human health risk assessment.

Weiss agrees the guidance is not clear.

Thomas doesn't want the Panel to make statements about the PBT approach because they have not reviewed it. On page 38 there are four references to PBT. What the scientific understanding is of how metals behave is different than what some agency office might want to do as a regulatory decision. Pittinger thinks it is under the panel's purview. Thomas responded that it depends on the application. Thomas wants to stay out of evaluating a scoring mechanism.

Speaking for the Agency Vu noted Question #7 asks you if the outline is reasonable and what kind of advice the Panel might have on the Framework. She noted that there are only four paragraphs on the Guidance, which makes that hard to review.

Pittinger responded that perhaps it is not yet timely to respond to the clarity and inclusiveness of the Guidance. When it comes to the Framework, EPA knows a lot about exposure which is not explicitly pointed out in the outline. He returned to his question about tiered risk assessment and tiered regulatory function.

Tran understands why the problem formulation is laid out that way and also that the tiered approach is often determined by the availability of the information rather than on the answers that you want. She struggles with how to make the relationship of data availability to the type of analysis more transparent. Pittinger gave a Superfund related example of a screening level risk assessment done early in a site-specific analysis.

O'Rourke suggested reversing the order of discussion of the topics tomorrow. Thomas didn't think it was needed.

CHARGE QUESTION # 8
Are there any additional actions, beyond those proposed in the Action Plan that could improve EPA's scientific assessments of the hazard and risks of metals?

Pittinger thinks this may be the place to discuss the differences between hazard and risk.

Friedland mentioned synergistic effects, susceptible populations and effects of metals on stressed systems. Weiss said they could also suggest the Framework pay more attention to the nutrition literature. O'Rourke mentioned adjuvant effects of metals. Metals are found in certain particulates where they will enhance immune responses. In Utah this has led to elevated allergic responses. Wiess raised the FQPA and spoke of exposure from multiple sources. He gave a smelter example. Speaking for the Agency, Vu mentioned cumulative risk.

The Panel Adjourned at 6:00 with writing assignments.

September 11, 2002

Panelists had prepared consensus responses to the charge questions on the evening of September 10. Their collected responses were ready for reading at 9:00. The text was available to the Agency and the public as well.

In the audience were:
SAB: Sue Shallal
EPA: Marc Stifelman, Region 10, Steve DeVito (OEI), Larry Rosengrant (OSW), Keith Sappington
Fed: Kevin Bromberg (SBA)
Public:Jane Luxton, Craig Boreiko (international Lead Zinc Research Organization), Bill Adams (Rio Tinto), Ann Smith-Reiser (Analytical Services, Inc.) By 11:30 there were only six people in the room (Boreiko, Luxton, Smith-Reiser, Stifelman, DeVito and Rosengrant At 2:15 there were four: Alec McBride (OSW), Stifelman, DeVito and Rosengrant. Jane Luxton was also present in the afternoon

At 9:30 Dr Thomas held a moment of silence in recognition of the anniversary of the events of September 11, 2002. Dr. Thomas then made a number of practical remarks about the revision of the document, the incorporation of disagreements, should they occur and additional points.

She then read the draft Executive Summary, observing that this element of the report is being discussed first today, because it has not been discussed before.

Weiss suggested that the Panel commend the Agency for letting us see this draft document at this early stage because SAB is often given a document to review when it is too late to do anything about it. In contrast, Thomas thought it hard to review something with so little content. It is very hard to give productive comments without some science in it.

O'Rourke thought there was another element. The Panel's major input is to speak to whether it makes sense to consider the adequacy of doing a document just about the differences of metals rather than a comprehensive document about metals.

Windom agreed with Weiss and also wanted the Executive Summary to say you can't treat metals like organic contaminants. He thinks EPA felt some obligation to do that and also to continue with the PBT approach. Before they go too far down that road, it would be nice if the Panel took some of the monkeys off their back. The Panel should also say, that while we feel that's what the process is all about, it is also hard to give much detailed advice because the plan is at such an early stage

Hayes agrees with Weiss and Windom. Like Thomas he was put off by having to go through a document that was less than clear, however, he would hate to see something way down the road – making them re-write their Framework would be way too much work. He wouldn't want to chastise the Agency, but the Panel's report should still recognize the difficulty of reviewing something at this stage.

Thomas said that, if the Panel is going to do that, we need to have some clear statements of advice and the report lacks them.

Windom just being able to say with agreement that the whole concept of persistence doesn't work here will save EPA from wasting time trying to grapple with it. Weiss thought the recent panel comments almost looked like a preliminary guidance documents.

Friedland likes the way people are making their recommendations. We should commend them for bringing it early, thank them for having brought this to us, and then say 4 of the 5 elements are correct. We disagree with the 5th and why. Then, he thinks, that we could suggest movement from speciation to environmental chemistry. It would be harder to make those changes 2-3 years down the road and well worth 3 days of our time.

Thomas noted that putting together this panel was a huge effort to get nationally and internationally recognized scientists without COI. EPA and the public have been here faithfully listening. One panelist quit because he thought the status of this document was not worth his time. Given that, the Panel should push hard to live up to the status it has received and give the Agency some clear guidance or admit it if it can't.

She made an analogy to a graduate student presenting a proposal for thesis or dissertation research.

The Agency has been pushing back on us when we comment. If it is useful we are doing a review at this point, there should be some real content.

Windom suggested that we could say that the Panel at first felt the document lacked clarity and focus. Then the Panel recognized that the Agency was suffering from the difficulty of trying to fit metals into the mold of organics and apply the PBT approach.

Hayes could understand quitting, especially after the August 29 call when we were told what we weren't supposed to be doing. To have a document be well written is

essential and this was not. Nor were the questions targeted in a way that made it clear what each of us was supposed to do. On the other hand, having moved forward into the process he feels we can do something positive and that we will be able to contribute.

Tran agrees with Hayes. She found the clarifications of the questions at the face-to-face meeting helpful because they focused the Panel on hazard. The draft Action Plan looked like it had more to do with risk.

Fowler agrees totally. The upside of coming in this early in the process is being able to guide EPA into making the Framework as good as it can be. It is a good professional contribution to do this.

Friedland returned to the student research proposal analogy. They don't fail people after the first year. They make corrections and clarify misunderstandings but also identify the "uncut" gems for them to polish.

O'Rourke thinks they need more clarity from EPA about where they want to go.

Friedland thinks they should say "This is what we think you mean and this is where we think you ought to go."

O'Rourke thinks the Panel wallowed from lack of context.

Thomas is willing to go with this.

Weiss is not clear about a sentence in para 2. Thomas said it was supposed to incorporate Windom's point on speciation. He suggested this change, "The issue of metals speciation should be considered under the broader umbrella of environmental chemistry."

Weiss finds the use of synergism inappropriate in the next paragraph. He would like combined effects of metals used instead of synergistic, antagonistic or additive.

O'Rourke backed up to bullet on persistence. She thinks the issue is that it is subsumed under the umbrella of environmental chemistry. She also think persistence is sometimes used to mean other things. Hayes would have said, "not be included as a major issue" Thomas argued that persistence somehow arose from the idea that, in considering prudence, we need to think about exposure over time. Windom disagrees, he thinks it means how long they hang around in the environment. Hayes says for organics, hanging around in the environment is a bad thing, but for metals it can be a good thing. Windom says that is why it is constructive to say don't include persistence. It is good if it is stable as a non-available term. Hayes thinks that EPA is on to the issue. Thomas thinks persistence has taken on a policy meaning and she would like the Panel's comments to stay out of policy. Nonetheless, time dynamics needs to be addressed, but calling it persistence is messy. Someway of dealing with time is

important and central to risk. Hayes and Windom says stability and half-lives are how geochemists deal with this. Pittinger prefers the Panel state that persistence in the context of metals is not what it is for organics and that preferred concepts are stability and half-lives.

Pittinger thinks one of the gems may be distinguishing hazard from risk. The draft Action Plan uses them somewhat synomously. Exec Sum bullets 1 and 4 confuse them. He suggests ". . . key issues in addressing hazards . . . in considering risk it is also necessary to include key elements of exposure." This way the Panel can set apart hazard and risk. O'Rourke said, in this context, there is also the issue of essentiality of metals which differentiates them from other environmental contaminants. Some metals have a role as essential nutrients, which is not true for many other chemicals. Hayes noted that the draft Action Plan stated several times that essentiality was a key characteristic of metals. O'Rourke says this plan lets all of exposure assessment hang out someplace else, but this difference about metals is so important that it must be elevated. Also, the underlying nutritional status will affect uptake. Hayes asked how high essentiality should be ranked. Weiss said the problem is the shape of the dose-response curve; O'Rourke added that is where the adjuvant element comes in as well.

Thomas felt uncomfortable with the statement that "this is what is different about metals" and would much prefer to think about "what would make metals risk assessments better." She thinks in some cases essentiality is critical, but not as critical as the four remaining issues and thinks essentiality should come in where we discuss what's been left out. Pittinger thinks essentiality could be brought into the discussion of bioaccumulation. Perhaps say something like, "Bioaccumulation is problematic to deal with for metals because of essentiality." O'Rourke says the discussion is dominated by lead, which is not essential for life. If we are considering metals as a whole then essentiality is important. Thomas pushed back with cadmium and O'Rourke countered with selenium and iron. Hayes said that whether or not we like the coverage or the extent of it in the Action Plan and that has to be recognized. Perhaps the Panel would like to change its emphasis or content.

Pittinger thinks the link to bioaccumulations is important. Hayes noted that public commentors Hamilton and Bromberg have both made those points

At 10:30 the Panel moved to Charge Question #1. Fowler read his changes.

Weiss asked how the Framework should be altered to accommodate Fowler's suggestions. Tran spoke of the Agency's approach as a "patch" on existing assessment documents.

The panel approved the content of Charge Question #1

At 10:45 The Panel discussed its response to Charge Question #2.

O'Rourke suggested switching bullets #1 and 2. Windom proffered a different editorial fix. O'Rourke says that one place EPA and the Public will gag is lead. Lead is persistent. Therefore, she is not sure we can go as far with the concept of persistence as she understands it – to the English word persist. Hayes says that example is why persistence has been used too broadly. That same quality of lead in a landfill is beneficial. O'Rourke said ecological risk can't dominate health. Windom said exposure, not persistence, is the issue. Thomas doesn't want to say things in a science sense that will be misread in a policy sense. She suggested the following wording, "The term persistence is problematic for metals and recommends that stability be used as a more fundamental scientific concept." DFO said that persistence, as currently used, seems to include both the concepts of stability and exposure. Thomas's fix only addresses one of these.

Thomas spoke of exposure. Persistence and bioaccumulation both get to exposure. She suggests that in addition to stability we talk about time variables. Windom and Hayes had talked about including something about environmental half-lives of metals in compartments. Hayes said the draft Action Plan gives an alternate definition of persistence. Pittinger disagrees with Di Toro's definition because it opens a vast morass of confusion; he thinks it is better to avoid the word entirely than have multiple meanings for it. Hayes "recommend the word not be used because of the confusion it causes" Thomas thinks we should say it is not a fundamental variable for metals.

In the context of Question 2 Bullet #3, O'Rourke commented on site-specific context. Bioaccumulation is an issue for metals when you end up with replacement of one element with another (such as lead for calcium) which can later become an in body source. Bioaccumulation has disease endpoint outcomes when you consider underlying nutritional status. This happens more with metals than other things. When you talk site-specific, she thinks of physical sites. If sites include human bodies than the thinks this is OK. Windom will take a sentence from her. Pittinger suggested that Windom should say WHY bioaccumulation is not useful – essentiality, hard to measure, inverse relationship, dose-response. He thought background could be woven in as well

Thomas said she disagreed with the whole 3rd bullet because she is not sure bioaccumulation is not a useful concept for a national hazard profile. She thinks Windom might have been thinking of BAF and BCF factors presented in public testimony which might not be appropriate. That's a more narrow question and the Panel didn't review it. Pittinger and Tran suggested characterizing it as a problematic issue. Tran said for national profiles you need a surrogate indicator; bioaccumulation seems to crude to be useful. Tran said yes, crude is OK, but inconsistency is not and bioaccumulation is inconsistent. Windom and Tran agreed there are some useful site-specific applications. Tran thought the Action Plan described these challenges very well.

Hayes thinks if you call this problematic they all are and suggested combining questions #2 and #3. Thomas suggests we keep the questions they way they are and give our answers as we wish, even if they don't match exactly.

Thomas asked for a more nuanced statement moved to the response to Question #3. Pittinger would like it kept and the difficulties of the concept kept along with a statement of its value.

Thomas is not keen about making statements about things we haven't reviewed, such as what should or should not be included in hazard ranking. Pittinger thinks of PBT as a hazard ranking scheme although there are no metrics and the Panel hasn't been asked to review it. He thinks there is a kernel to this exercise which is the applicability of PBT developed for organics to metals. Thomas agrees PBT is a hazard ranking scheme. She would want to look at it carefully before deciding that there is something not appropriate. Pittinger agrees it might be too strong to say not useful.

After the break the Panel spoke briefly about a revised plan for mechanics of the report. 12:30 seems unrealistic given the slow progress of the morning. People will continue to feed their revised materials to the DFO. Tran has a computer that reads diskettes and can do email and will assist chair and DFO with the mechanics.

At 11:30 the Panel began discussion Question #3.

Hayes read it. O'Rourke suggested that eventually the chair or DFO do a word search for ecological and see if ecosystem can be used instead to avoid confusion with epidemiological ecological study design. Hayes and Windom will work on the third bullet so that it is coordinates with the matching discussion under Question #2.

Regarding the Bullet #4 discussion of bioaccumulation, Pittinger suggested "can be problematic" rather than "should not be used" and strengthening with the points made above. As well as background reference levels in the environment.

Weiss noted that using bioavailability in this context will throw off toxicologists and health scientists. O'Rourke asked about biomagnification. Hayes said there were so many terms and it isn't his area. Windom said that, in the case of food chains, bioaccumulation always implies biomagnification. Windom thinks this is the key nut to crack to deal with metals – we know where metals are, but we have a difficult time knowing how available they are to organisms. Thomas does agree that bioaccumulation may be a better scientific focus issue, but parts company over assessing risk and hazard. She doesn't like making recommendations about things the panel hasn't reviewed. O'Rourke suggested ending the sentences at scientific focus issue. Hayes and Friedland agreed.

O'Rourke has one more issue on bioavailability. Imagining herself as a risk, hazard, or exposure assessment, what term is she using for bioavailability. Because it is organism specific and has to have some context, what should she use. Thomas

agrees we don't know. The Framework and Guidance have not yet been developed. Pittinger thinks it is as vague as environmental chemistry and appropriately so.

Regarding Question #3 Bullet #5, Pittinger thinks this might be the place to say metals are different than organics, should be treated differently, and this should be in the executive summary. Friedland says bullet #5 says that the document is good because it points out that metals are different from organics. Thomas says, again, that as a reviewer she has not seen the PBT approach. Hayes did look at the literature so that he could review his section and he found out what everybody else already knew, that it was all about organics. Hayes thinks it may be positive to say, "Don't get stuck in this mind set. Start with an open mind." Tran says if we start with hazards we may be able to say that persistence and bioaccumulation may not apply. Is T ,T? The Waste Min Prioritization Tool uses QSTAR and other dose response measures for T. She is uncomfortable making a statement that the PBT approach is irrelevant. Pittinger thinks maybe method or approach is the problem and really what we are concerned about is the criteria. Tran thinks this gets you away from the policy questions and we should be contributing on the science. Pittinger agrees with Thomas we haven't reviewed an approach. Hayes likes the change to criteria from approach. Pittinger said we could drop it all together. Thomas thinks that set of letters (PBT) together means something . . . and it isn't what the Panel reviewed. O'Rourke brought the Panel's attention to page 38 of the Action Plan. Someone said it might be page 27. Pittinger has been swayed by Thomas – we've been asked to look at five criteria, not PBT.

Friedland suggests getting rid of this bullet. Hayes would like a bullet that says we shouldn't think of metals like organics. There was general agreement that this should be in the Executive Summary and therefore has to be in the body and should be the first bullet in this area. Thomas says that, in some cases – even many cases, metals are different than organics, in some cases (such as the organo-metals) they are quite alike. Windom says TBT should be treated as an organic, but methyl mercury is different. This statement is going to need to be nuanced. "Panel strongly agrees that in many contexts metals need to be treated differently than organics." Pittinger asked whether there were always questions of essentiality and background reference levels. Thomas compared EPA's big assessments of dioxin and mercury and said they were both the same horrible difficult process. Pittinger said the process was the same, but some of the considerations were different. Hayes says if they behave as organics, they can be treated as organics. Thomas said when you are doing a risk assessment, there you are looking at issues of exposure and the driving issues and uncertainties are largely the same for metals and organics. These issues aren't included in the Framework because they are the same.

Weiss said that if you go down a series of steps in the final risk assessment process, at what point to they diverge? Hayes thinks they diverge at ranking.

Regarding Question #3, bullet #6, O'Rourke doesn't have a problem with it because it is fundamentally true. However, since the MAP has a life span of two

months, then does this truth matter? Hayes said it basically means, “Don’t necessarily take those issues forward into the Framework without thinking about them because they aren’t supported?” White papers will help. Weiss says this is very vague unless you have the document in front of you. Tran suggested the details go in an appendix.

At 12:15 the Panel began discussing Question #4

O’Rourke made notes of things here that she didn’t want to get lost. She thinks that much of the paragraph on the four issues can be deleted because it has already been said, with the exception of the discussion on adjuvant.

The short answer to the question is No.

Pittinger asked if this was an opportunity to separate risk and hazard. He thinks she’s got it for hazard. The context he is thinking of his exposure which is critical for ranking risks. He suggested that exposure be mentioned as a priority for risk. While the question asks for priorities within the list of issues, perhaps we could say that within the list we think such-and-such and beyond the list, we note that exposure is important to risk assessment.

Tran thinks we may have a different idea of what this answer should be. Her first cut was hazard, Friedland’s was on where the knowledge is. There was some convergence on bioavailability and environmental science. Toxicity hasn’t been discussed much.

Thomas thinks that it is inherently confusing to understand what we would mean in our discussion of priorities. The Panel has been confused about it. EPA thinks the Panel is confused. She’s afraid the reader will be confused about what’s important for risk assessment, for research, etc.

Could just stop at “without a context.” Fowler thinks this could be a workshop issue. Tran suggested that, if we can’t address part (a), perhaps we could address part (b). Weiss suggested we keep current response to (a). Thomas would suggest dropping “Global prioritization” sentence should be dropped.

The Panel discussed the minority review. Hayes, who is serving on a relevant NRC panel, thinks bioavailability would be important to risk assessment. Tran asked if there is enough available to be useful . (Enough what?) Yet, if we say there’s no context . .. Perhaps he can say that, on the ecosystem side the two issues . . . For ecosystems the panel recognizes speciation and bioavailability as the key issues in generation . . . recent advances in speciation and bioavailability could reduce uncertainty.

Regarding O’Rourke's illustrative Table #1, Thomas thinks we should only have a matrix if we can fill it in, not a concept. We could say a concept in words. She doesn’t think the panel will fill it in. How do others feel. Friedland thinks it’s a nice idea but

doesn't feel strongly. Windom doesn't understand it. O'Rourke was getting at whether there was enough knowledge in those areas to move forward with a Framework and Guidance. Thomas thinks that, if we are going to have a matrix, we need more discussion of it – what are the rows and columns, are they the right ones. O'Rourke doesn't have a problem with taking it out. Weiss thinks it is a useful example for how EPA could go about looking at the state of the science. Otherwise you end up with flimsy generalizations. Pittinger says it is one matrix and one way of organizing the state of the data. EPEC did a long-winded ad hoc environmental indicator report which identifies seven essential attributes by which risk assessors would identify essentially all endpoints. (biotic communities, natural disturbances, etc.) In thinking about it, he could think of several places where metals could play key roles. O'Rourke suggested we could float that matrix. Tran likes the matrix, but isn't sure she wants it here in the context of this charge question. It's misplaced. Perhaps could just suggest a systematic evaluation of the state of the science and the state of the data to determine what is feasible and what's not.. Windom had some general language. Hayes thinks this is the question to ask after we get the white papers.

After a late lunch, the Panel began discussion of Question #5 at 2:10. Tran led the discussion. Everyone seem to feel the final paragraph under Clarity on Receptors should be the key recommendation and said earlier. Overall the direction was to make it shorter.

Regarding Public Health Surveillance data, Friedland recommended something parallel was needed for environmental data -- perhaps this could be called ecosystem surveillance data. Hayes thought that the last sentence is the summary and should go first.

Metal Mixtures is unclear because NHANES has been measuring metals for a long time. Weiss would like to deal with the problems of mixtures and prevailing body burdens because they are related to each other. An environmental mixture of metals has to be seen in the context of what we already possess as a body burden. Thomas asked, "Are you saying metals mixtures are important, not just in Superfund sites, but in humans?" Friedland wrote something that merged his writing and Weiss's that might address mixtures and humans; he will show it to Weiss. Friedland asked if there was too much text. Everyone seemed to think briefer would be better. Weiss mentioned the work by nutrition scientists and the Mertz paper he provided. Weiss said, that the assessment of mixtures in the environmental cannot be assessed independent of body burdens in the exposed population.

Relevant time frame/duration for metal risk assessment – Thomas liked the general discussion, but not the discussion of truncation. O'Rourke thinks time is just one of many exposure parameters. She doesn't object to anything that's there, but she does note that it is an uneven treatment of elements that are important in exposure. Pittinger noted frequency,aggregate cumulative exposure and duration of exposure are also important. We could consider expanding or moving, but it is still a valid point.

At 2:30 the Panel began discussion its response to Question #6. Weiss observed that the process seems to change shape like an amoeba, the timeline is very tight, and more novel outreach is warranted. Windom differs from Weiss in that he thinks the Framework is needed before the Guidance can be developed. Windom says the panel may be talking the talk, but they aren't the folks who have to walk the walk. Therefore the people who really have to do it at the lowest level who have to do the work need to understand it and have input into what works and what doesn't work. Could there be pilot projects?

Thomas is concerned about the Guidance document which she interprets as guidance on how to rank metals. There's not a lot of science agreement about that. Guidance implies the experts know how to do it and are just writing it down for the guys in the field. There are some examples that could be done. O'Rourke said that if EPA doesn't bring in a balanced group you could end up with schemes dominated by one external group or another. Everyone needs input, but how will the document come together. For the communications component, she's not sure she wants EPA to invest a lot of energy in new ways of communicating. Weiss agrees that the components of the traditional approach need to be there also, but he would like to see them reach out a little further, say, to nutritionists. Friedland says it sounds like some of the panel are agreeable to this approach but that 2.5 pages is longer than the other responses. Could it be edited down while retaining the tone of challenge to do something innovative.

Friedland thinks he can shorten the first 4 paras, needs help with the last page and a half. Thomas suggests the paragraph on schedule could be cut in half. She also thinks we shouldn't push EPA too hard to do the IED approach, we could point them to it without pushing quite so hard.

Friedland will cut to one page, pass by Weiss, and give to DFO

At 2:45 the Panel began discussing its response to Question #7. Pittinger now feels his answer is too long. It addresses several of the issues the Panel discussed. He will suggested a couple of these be moved to other sections. He might re-organize the section to get rid of the division between hazard and risk.

Aligning Regulatory Functions with Tiered Risk Assessment. The middle para can be dropped if we assume everyone has this background. He contends that the three regulatory functions do not consistently meet the mold of tiered risk assessment. Hayes and O'Rourke agreed this is a problem. Thomas felt the problem reflects sloppy writing rather than true confusion in EPA's minds.

Making the Distinction Between Hazard and Risk. Thomas suggests cutting out how the stuff on "in the introduction . . ." Pittinger suggested starting the next sentence with "The Agency" and Windom suggested that sentence should be the first one. O'Rourke indicated the first sentence should be the topic sentence.

Pittinger thinks that the Framework is more about risk assessment and the Guidance more about hazard ranking. Thomas thinks they should say that the specific purpose and content of the Framework and Guidance documents is still not clear. Windom read from the Executive Summary of the draft Metals Action Plan, "Whereas the Framework will consider issues and principles applicable across EPA's regulatory activities, . . . the Guidance for Characterizing and Ranking Metals . . . will provide the tools and specific guidance for characterizing and assessing the hazards and risks of metals and it will address critical needs identified by the stakeholders.

Tran thinks risk assessors know so little epidemiology that they won't misunderstand ecological risk assessment, but will get mixed up by endpoints which mean different things in ecology and human health.

At 3:00 the Panel began discussion its response to Question #8. Friedland asked, "Is there too much on sensitive sub-populations stressed by other agents? Or should it be someplace else?" Tran thinks it sounds good and should be left as it is. Fowler and Weiss agree.

Regarding, multi-media exposures – O'Rourke thinks it might be in the last para of response to Question #1. Consensus seems to be to leave it here. Tran is influenced by the definitions in the FQPA which is also an EPA policy, based on science. Aggregate means same chemical, same source, different paths. Cummulative means several chemicals with the same mode of action. O'Rourke referred to page 36 of the draft Metals Action Plan and asked whether we need to say it if the risk assessor is the target audience. Pittinger thinks it is good to say it is relevant to metals as well as foods and drugs. O'Rourke is happy with it as written. Fowler said Friedland could mention multiple sources.

Friedland's last para was intended to capture one of O'Rourke's points, but didn't. She wanted to bring out the adjuvant effects of metals which need to be considered because they can enhance a disease outcome. She also talked about trace metals in fine particulate, whether from smelters or diesel exhaust, that might relate to a disease outcome.

Friedland asked why this wasn't toxicity. O'Rourke said it is a stimulant to the immune system. Thomas charged Fowler and O'Rourke with writing this carefully.

Pittinger asked Friedland and O'Rourke whether the Panel has dealt adequately with the beneficial effects of metals. Should we keep the current last para, even though it isn't the point O'Rourke meant to say. O'Rourke thinks not because it gets you back into the bioavailability issue. Weiss thought it might make more sense to focus on the shape of the dose-response curve and Friendland suggested, "there's a risk of having too little and a risk of having too much."

At 3:30, while the DFO was integrating the panelists edits into a revision, Thomas asked whether anyone in the audience would like to make some comments in about 45

minutes and there were some people who were interested. First there will be a writing period. She hopes that people will have written what they need to by

By about four, the Panel had finished its writing and the DFO incorporated the revisions into a single file, had it printed and copied. During this time the Panel heard speakers from EPA including: McBride, Sappington, DeVito, and Wood.
The DFO heard only crumbs of these talks, but returned with the "end of the day" draft in time to hear two members of the public speak. Ann Smith-Reiser, a contractor for DOE who does not speak for them, thanked the Panel for their efforts and said lots of people are interested in what the Panel is doing. Jane Luxton of King and Spalding agreed with Smith-Reiser and DeVito that it is important the SAB review this. She encourages the Panel not to hold back if they question the use of persistence, bioaccumulation, and the PBT concept for metals. This morning she heard questions about the importance of persistence and bioavailability and getting the monkeys off EPA's back. She hasn't seen the latest draft but senses that there is some retrenching. If you look at pages 17-28 of the draft Metals Action Plan you will see how PBT and other approaches are being used by various programs at EPA. She thinks the Panel has enough information before them to speak to this issue and they should. The Panel was selected for their expertise on metals and it would save everyone time and resources if EPA need not spend time going down unproductive paths.

The DFO distributed the second draft of the day at 4:45. Thomas asked that panelists go over the Executive Summary carefully, because it is at a younger stage than the rest of the document. One suggestion is to review the input we heard, identify the points and consider if we want to make changes and how. We have to read at least the Executive Summary. If we had the energy, we could read the whole plan.

Fowler thinks that the Panel could read the Executive Summary carefully and the Answers to the Charge Questions quickly and discuss them before leaving.
Thomas asked the Panel to read now, flag problems and check off what is OK.

At 5:20, the Panel finished reading the most recent draft. Dr. Thomas summarized comments from EPA for consideration as potential edits for the draft.

1. Sappington felt that bioaccumulation is important and the issue is how to measure it. Windom thinks the previous draft did downgrade it and the current draft does not. O'Rourke said on page 7 "inasmuch as . . ." indicates that bioavailability was elevated relative to bioaccumulation. Pittinger thought Sappington thought bioaccumulation was important but could be treated as part of bioavailability. He believes the current response to the charge question reflects the Panel's thinking, but the text in the Executive Summary does not. Thomas will fix by having bioavailability subsume bioaccumulation.

Sappington's key point was that the Panel should offer an opinion on whether organo-metallics should or should not be included. Windom thinks it is a mix of apples and oranges because there are synthetic organo-metalics. Windom thinks that if it

forms organic compounds under natural conditions, it should be considered. Thomas suggested Windom include this under Question #3 page 6. He wasn't enthusiastic. Friedland said that it is included in the last full paragraph on page 4. Fowler thinks Thomas could include it in the Executive Summary on page 2. O'Rourke said "including man-made and naturally occurring organo-metalics." Windom said that synthetic organo-metalic compounds are a different kind of problem. Thomas thinks there are many cases when metals can be treated like an organic; therefore, there should be flexibility. While Windom thinks environmental chemistry and speciation covers organo-metalics, Fowler and Friedland favored making that explicit at least once in the text.

2. Alec McBride clarified both how EPA was thinking about the words hazard and risk and how EPA was thinking about the different kinds of tiering. Friedland read it that they could have been more careful about the use of hazard and risk. The general sense is that the comment should stay in but there's no need to browbeat the Agency. Similarly on tiering.

3. DeVito brought up synergisms, noting that it is really hard to do a risk assessment for one metal and mixtures are beyond them. Fowler intends that, even if EPA can['t do it now, there should be a placeholder so that when the science develops O'Rourke suggested something go at the very end of Q#5 and asked Fowler provide contacts of those active in the area to Tran. Friedland thinks it's clear enough.

4. Luxton pushed for stronger statements on PBT and on P and B. Windom thinks the Panel is doing that. Friedland thinks that's a comment best addressed when we are fresh in the morning. Pittinger thinks it is important that this be clear in the Executive Summary and we have to be careful about not being quoted out of context.

At 5:45 the Panel began discussing the Executive Summary

Weiss had some suggestions about phrasing. All agreed that "Persistence is not a fundamental property of metals" needed to be changed. Weiss suggested, "Persistence is not a property that can usefully be applied to metals hazard and risk assessment." "Persistence is a fundamental property of all metals and so has little or no value in discriminating among metals, hazards and risks." O'Rourke "Stability and environmental residence times are better temporal characteristics than persistence for metals.

The Panel decided to beef up the Executive Summary by giving a brief rationale for each of the bulleted items.

Tran asked whether surveillance data should be in the Executive Summary. Thomas thought this might be addressed under the one on exposure. Tran took last sentence from page 9. EPA should evaluate approaches to incorporate public health, environmental and ecosystem surveillance data in the metal risk assessment framework.

The second bullet does not convey to Pittinger the same thought process as the text on pages 6 and 7. He would like the Inasmuch statement on page 7 brought forward. Friedland thinks “The SAB agrees that speciation (under the umbrella of environmental chemistry), bioavailability, bioaccumulation, and toxicity are the key scientific issues.” Pittinger thinks maybe we need a separate bullet on bioaccumulation and suggests While it can be useful . . . metrics can be problematic.

Does the subsuming of bioaccumulation into bioavailability conflict with the four issues?

Friedland, thinks we want to keep 4 out of 5 are correct.

Metals should be treated differently than organics because of essentiality and natural background.

Tran suggests rearranging bullets so that 3rd, which deals with exposure, comes later near combined effects. Maybe add a few after speciation. Pittinger likes the elaboration on first bullet and moving exposure down. It seems to relate to hazard and risk. It looks like there are three statements qualifying persistence, speciation, and bioaccumulation.

September 12

The Panel had revised its report again Wednesday evening. This revised report was available to the Panel, the Agency and the Public at the start of the meeting. After a reading period, the Panel again reviewed the report, section by section. Some editorial improvements were suggested with the responses to Questions #6 and #8 receiving some enrichment. While recommending edits, the Panel was comfortable with the content of the draft.

At 10:30 the Chair summarized the report for the Agency and the public by reading the Executive Summary. (In some cases, this highlighted areas where the wording could be made smoother.) She asked for a response by the Agency, received a couple of technical comments from Keith Sappington and Steve Devito. Bill Wood summarized for the Agency saying that the advise responded to the charge, was understood, and was appreciated. He thanked the panelists for their efforts.

The Panel approved the report pending an opportunity to confirm that the requested changes were made. Dr. Thomas explained that the Panel's report was not SAB advice until it was approved by the Executive Committee and briefly explained that process. Someone asked when the Executive Committee would review it. Vanessa Vu, acting as Director of the SAB Staff said that the EC was meeting October 1-2 and, if the Panel was sure it would have its report available by Tuesday September 17, she would arrange for a Federal Register notice to be issued adding this item to the Executive Committee's agenda. The Panel agreed this could – and would – be done.

Dr. Thomas adjourned the meeting shortly before noon.